

THE WORLD ANTI-DOPING PROGRAM

**GUIDELINES FOR
ANTI-DOPING ORGANIZATIONS
DEVELOPING BEST PRACTICE
DOPING CONTROL PROGRAMS**

**GUIDELINES FOR TRANSITION
FROM ISO/PAS 18873:1999
TO THE WORLD ANTI-DOPING
PROGRAM**

**An
International Anti-Doping Arrangement (IADA) – World Anti-Doping Agency (WADA)
Collaboration**

**Version 1.0
14.06.04**

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Annex A – Overview comparison between ISO/PAS 18873:1999, the International Standard for Testing, the World Anti-Doping Code and ISO 9001:2000

1.0 Purpose

These Guidelines are written for anti-doping organizations with an existing quality system for doping control that is compliant with the requirements of ISO/PAS 18873:1999 (ISO/PAS). Such quality systems will need to be modified in some aspects in order to meet the requirements of the World Anti-Doping Program (WADP). This document is designed to provide an overview comparison between the requirements of the ISO/PAS, the WADP and ISO 9001:2000. Its purpose is to provide helpful information for the transition process rather than solutions to the issues identified. Therefore anti-doping organizations will need to undertake a more detailed analysis of their existing quality systems and the new requirements to ensure compliance with the WADP.

2.0 Scope

Using the main elements in the doping control process this document identifies the key changes between the requirements of the ISO/PAS and those of the WADP. Additional mandatory requirements specified in the WADP are also highlighted. The main elements in the doping control process have been defined as planning, notification, preparation for sample collection, sample collection, post test administration, sample analysis, results management, hearings and appeals, and also include requirements relating to sample collection personnel.

Annex A cross references the requirements of the ISO/PAS with similar requirements of either the WADP or ISO 9001:2000, and also notes additional WADP requirements.

3.0 Background

In 1996 the International Anti-Doping Arrangement (IADA) introduced the IADA Quality Concept which included the development of the IADA Standard for Doping Control (ISDC) and its appendices of Common International Quality Documentation. In addition to providing a best practice model for doping control programs, the purpose of the ISDC was to encourage harmonization and best practices in all doping control activities. The ISDC and its appendices were recognized by the International Organization for Standardization (ISO) and published as ISO/PAS 18873:1999. The IADA Quality Concept involved the development, implementation and certification of quality systems for doping control in accordance with the requirements of ISO 9001:2000 and the ISO/PAS. The Quality Concept has now evolved to be consistent with the World Anti-Doping Program which was established in 2003.

The World Anti-Doping Program (WADP) is administered by the World Anti-Doping Agency (WADA), and includes the World Anti-Doping Code (WADC) and mandatory International Standards. The requirements within these documents were developed by WADA in consultation with anti-doping organizations. The objective of the WADP is to ensure that anti-doping organizations carrying out doping control programs and related activities are adhering to a set of minimum requirements collectively recognized as applicable and acceptable for all sports and countries. As a consequence, this will enhance the harmonization and effectiveness of doping control programs worldwide. Models of best practice and Guidelines have also been developed as part of the WADP.

WADP Level 1	The World Anti-Doping Code	(mandatory)
WADP Level 2	International Standards	(mandatory)
WADP Level 3	Models of Best Practice/Guidelines	(optional)

In addition to complying with the WADC and mandatory International Standards, IADA and WADA are recommending that anti-doping organizations develop and certify their doping control programs in accordance with the requirements of the ISO 9001:2000 Quality Management Systems standard.

4.0 New Scope of Certification

For ISO 9001:2000 certifications of quality systems for doping control, the transition to the WADP requires changing the scope of certification from the ISO/PAS to the requirements applicable to doping control programs and related activities specified in:

- The World Anti-Doping Code
- The International Standard for Testing
- The International Standard for Therapeutic Use Exemptions
- The Prohibited List International Standard

The quality system will also need to be in compliance with the ISO 9001:2000 Quality Management Systems standard.

In addition to these mandatory requirements, anti-doping organizations may expand the scope of certification by developing quality systems which comply with the following recommended guidelines aimed at achieving a higher level of best practice:

- World Anti-Doping Program, Level 3 Models of Best Practice and Guidelines
- ISO 9004:2000 Quality Management Systems - Guidelines for Performance Improvements (which is recommended to provide further guidance on developing a quality management system for doping control with particular emphasis on management-led improvement and using a quality system as a management tool)
- ISO 19011:2002 Guidelines for Quality and/or Environmental Systems Auditing

Guidelines for certification agencies have been developed by IADA and WADA to provide for consistency and reliability in the certification process as a valuable means of ensuring that quality systems are achieving harmonization worldwide. WADA will identify on its website, or by other means of publication, those anti-doping organizations that have achieved ISO 9001:2000 certification issued in accordance with the Guidelines for Bodies Operating Certification of Quality Systems for Doping Control Programs.

5.0 Main Changes from the ISO/PAS to the WADP and ISO 9001:2000

The following sections highlight key transition issues and do not present a comprehensive comparison between the ISO/PAS requirements and those of the WADP and ISO 9001:2000. As noted at the beginning of the Guidelines, anti-doping organizations will need to undertake a more detailed analysis to ensure compliance with the WADP.

5.1 General

- There is an increased focus on achieving harmonization by developing systems that are in compliance with a set of minimum requirements. The ISO/PAS focused on best practice policies and specifications for doping control involving urine sample collection. The WADP identifies minimum requirements for the different elements of the doping control process (e.g., minimum testing pool and whereabouts information requirements for planning an effective distribution of doping control tests).

- The scope of the International Standard for Testing (ITS) extends to include both blood and urine sample collection.
- WADA, rather than the IOC, is the main authority for requirements and accreditation of laboratories.
- The scope of anti-doping rule violations has increased, particularly relating to athlete whereabouts information and athlete support personnel.
- The WADC includes requirements related to the International Standard for Therapeutic Use Exemptions (TUE), mutual recognition and sharing of information between relevant authorities, and reporting to WADA.
- The WADC provides clarification of roles and responsibilities for event testing, out-of-competition testing, results management and sanctions.
- WADA has committed to providing infrastructure to enable stakeholders to easily share and report information pertinent to doping control.
- The quality system and quality management requirements in the ISO/PAS are contained within the ISO 9001:2000 standard.
- The frame conditions for anti-doping organizations in the ISO/PAS are partly rewritten in general terms and presented in the WADC or mandatory International Standards. Detailed descriptions are not presented as such in the WADC or mandatory International Standards. However, aspects such as sample collection personnel requirements, education programs, anti-doping research and annual statistical reports have been included.
- Requirements relating to “Policies and Standards for applying ISO 9002 to Doping Control” in the ISO/PAS are now defined, in general terms, in the ISO 9001:2000 and also in the “Guidelines for bodies operating certification of Quality Systems for doping control programs” (Certification Guidelines).

5.2 Definitions

Many of the definitions in both the ISO/PAS and the WADP have similar intent. However the definitions contained within the WADP now supersede those contained within the ISO/PAS. Some key changes are:

- Definitions in the WADP are more comprehensive and contain legal elements.
- The WADC and ITS have defined a number of terms that are not defined in the ISO/PAS. Examples include “doping control”, “event”, “ineligibility”, “minor”, “registered testing pool”, “sample/specimen”, “testing”, “blood collection official”, “sample collection equipment”, “sample collection session” and “weighted” testing.
- Some of the defined terms increase clarity and/or specificity such as the definitions for “no advance notice”, “in-competition”, “international-level athlete”, “athlete support personnel” and “anti-doping rule violation”.
- Terms related to quality systems and quality management defined in the ISO/PAS have not been included in the WADP. These definitions are specified solely in the ISO 9000:2000 Quality Management Systems - Fundamentals and Vocabulary.

5.3 Testing processes

Key changes between the requirements of the ISO/PAS and those of the WADP are highlighted below according to the process flow for testing. The key changes have been identified by comparing the requirements in the ISO/PAS to the relevant sections of the WADC and mandatory International Standards.

A. Planning

ISO/PAS	WADC	ITS
2.1, 2.2.1 – 2.2.10	2.4, 5.1, 5.2, 10.4.3, 14.3 – 14.5	4.0

Key changes:

- Minimum requirements for athlete inclusion in the registered testing pool have been defined, including specific responsibilities for national anti-doping organizations and international federations.
- Anti-doping organizations with overlapping registered testing pools are to coordinate that aspect in developing their test distribution plans.
- Minimum requirements for athlete whereabouts information have been defined, including special provisions for athletes with disabilities if required.
- Athlete responsibilities for providing whereabouts information and consequences for non-compliance have been defined.
- Athlete support personnel must not be involved in test distribution planning for their athletes.
- Target testing, as well as weighted and random selection methods, must be used for selecting athletes for sample collection.
- Minimum requirements have been specified for maintaining test distribution planning data for each test and each adverse analytical finding.
- Anti-doping organizations are required to provide their registered testing pools, athlete whereabouts information and other specified test distribution planning data to WADA for facilitating planning and coordination of testing.

B. Notification

ISO/PAS	WADC	ITS
2.2.11 – 2.2.19 IADA 200, 201	2.3, 5.2	5.0, Annex B

Key changes:

- Increased priority has been given to no advance notice testing.
- Advance notice testing is restricted to exceptional situations.
- Provisions for minors, athletes with disabilities and athletes requiring special assistance have been specified.
- Anti-doping organizations are required to define what constitutes reasonable attempts to locate an athlete for testing, and to investigate a possible failure to comply when such attempts are unsuccessful.
- Minimum requirements for identification cards/documents for sample collection personnel have been defined.

C. Preparing for the sample collection session

ISO/PAS	WADC	ITS
2.3.1 – 2.3.8 IADA 300	5.2	6.0, Annex B

Key changes:

- Minimum requirements for a doping control station have been defined.

- Minimum criteria for who can be authorized to be present during sample collection sessions have been defined.
- Provisions for minors, athletes with disabilities and athletes requiring special assistance have been specified.
- Minimum requirements for sample collection equipment have been defined.

D. Conducting the sample collection session

ISO/PAS	WADC	ITS
2.3.9 – 2.3.14 IADA 202, 202.1, 203, 203.1, 203.2, 203.3, 205	5.2	6.3.3, 7.0 Annexes A - F

Key changes:

- Blood collection requirements have been defined.
- Provisions for minors, athletes with disabilities and athletes requiring special assistance have been specified.
- There is reference to standard health precaution requirements when collecting samples.
- Requirements have been specified for target testing and investigating possible failures to comply when samples do not meet laboratory standards for analysis for reasons other than natural causes.
- Minimum requirements for documenting the sample collection session have been defined.

E. Post test administration and transport of samples

ISO/PAS	WADC	ITS
2.3.15 – 2.3.17, 2.4 IADA 204, 206, 302	5.2	8.0, 9.0

Key changes:

- There are no specific references to transport bags and sealing transport bags.
- Anti-doping organizations are to define criteria to be followed by doping control officers for securely storing sealed samples at the doping control station.

F. Sample analysis

ISO/PAS	WADC	ILS
2.5 IADA 301	6	All sections

Key changes:

- Requirements relating to sample analysis are now contained in the WADC and the International Standard for Laboratories (ILS).
- WADA, rather than the IOC, is the main authority for laboratory requirements and accreditation.
- Where analysis of a blood sample will not be performed at a WADA-accredited laboratory, the facilities and/or methods for the blood sample analysis are to be approved by WADA.

- The choice of WADA-accredited laboratory or other WADA-approved method for sample analysis is to be determined exclusively by the ADO responsible for results management.

G. Results management (including therapeutic use exemptions)

ISO/PAS	WADC	TUE	Prohibited List
2.6	4.4, 7, 13.3, 15.4	All sections	S4

Key changes:

- Requirements have been defined for an initial review following an adverse analytical finding and prior to taking other action.
- Requirements have been specified in the Prohibited List International Standard for follow-up investigations and related notifications for certain adverse analytical findings.
- B-sample analysis is only conducted upon the athlete's request.
- Requirements for investigations of non-analytical anti-doping rule violations and related notifications have been defined.
- Requirements to have a process in place for athletes to apply for therapeutic use exemptions have been specified.
- Requirements for handling applications for therapeutic use exemptions have been defined in the mandatory International Standard for Therapeutic Use Exemptions (TUE).
- Anti-doping organizations are required to provide WADA with documentation for all therapeutic use exemptions.

H. Disciplinary procedures, sanctions and appeals

ISO/PAS	WADC
2.7	8, 9, 10, 11, 13, 14.1 – 14.2

Key changes:

- A hearing conducted in accordance with specified principles is required to determine an anti-doping rule violation.
- Requirements for disqualifications and sanctions for the different types of anti-doping rule violations have been defined.
- Requirements are given for what can be appealed, who can initiate appeals, and which bodies can hear and decide appeals. Within these requirements, WADA and the relevant international federation can appeal national determinations of anti-doping rule violations, sanctions and appeals.
- Requirements have been specified for notifications and reporting of outcomes of anti-doping rule violation hearings, sanctions and appeals.

I. Sample collection personnel

ISO/PAS	WADC	ITS
3.1.5	5.2	Annex G

Key changes:

- Requirements for blood collection officials have been defined.

- Minimum requirements for training programs, accreditations and re-accreditations have been defined.

Annex A – Overview comparison between the ISO/PAS 18873:1999, the International Standard for Testing, the World Anti-Doping Code and ISO 9001:2000

The following charts list primary corresponding sections.

ISO/PAS Requirements	Content	ITS	WADC	Content
2.1	Test Distribution Planning	4.0		Planning
2.2	Selection and Notification of Athletes	5.0		Notification of Athletes
2.3	Preparing for and Conducting the Sample Collection Session	6.0 7.0		Preparing for the Sample Collection Session Conducting the Sample Collection Session
2.4	Handling of Samples	8.0 9.0		Security/Post Test Administration Transport of Samples and Documentation
2.5	Sample Analysis		6.1 6.4	Use of Approved Laboratories Standards for Sample Analysis and Reporting
2.6	Results Management		7 4.4	Results Management Therapeutic Use
2.7	Disciplinary Procedures, Sanctions and Appeals		8 9 10 11 12 13 14.1-14.2	Right to a Fair Hearing Automatic Disqualification of Individual Results Sanctions on Individuals Consequences to Teams Sanctions Against Sporting Bodies Appeals Confidentiality and Reporting

ISO/PAS Procedures	Content	ITS		ISO 9001	Content
		Sec.	Annex		
IADA 100	Procedure for changing and controlling the IADA Standard for Doping Control			4.2.3	Control of documents
IADA 101 IADA 101.1 IADA 101.2	Procedure for producing quality system documentation Template for producing quality system documentation Template for producing quality system documents: guidelines			4.2.3	Control of documents
IADA 102	Procedure for changing international quality documents			4.2.3	Control of documents
IADA 103	Procedure for controlling international quality documents			4.2.3	Control of documents
IADA 200	Procedure for athlete notification: no notice	5.3 5.4			Requirements prior to notification of athletes Requirements for notification of athletes
IADA 201	Procedure for athlete notification: short notice	5.3 5.4			Requirements prior to notification of athletes Requirements for notification of athletes
IADA 202	Procedure for conducting the sample collection session: chaperoning in waiting room	7.3			Requirements prior to sample collection

IADA 202.1	Work instructions for conducting the sample collection session: chaperoning when athlete temporarily leaves waiting area				
Additional WADP Procedures			B D G		Modifications for athletes with disabilities Collection of blood samples Sample collection personnel requirements
IADA 203 IADA 203.1 IADA 203.2 IADA 203.3	Procedure for conducting the sample collection session: collection of urine sample Guidelines for conducting the sample collection session: laboratory volume and quality requirements for samples Work instructions for conducting the sample collection session: insufficient sample Work instructions for conducting the sample collection session: checking the sample is fit for analysis		C E F		Collection of urine samples Urine samples – Insufficient volume Urine samples – Samples that do not meet laboratory pH or specific gravity guidelines
IADA 204	Procedure for conducting the sample session: security/post test administration	8.0			Security/post test administration
IADA 205	Procedure for conducting the sample collection session: processing possible failures to comply		A		Investigating a possible failure to comply
IADA 206	Procedure for handling samples	9.0			Transport of samples and documentation

Specifications	Content	ITS	WADC	ISO 9001	Content
IADA 300	Recommended specifications for purchasing sample collection equipment	6.3.4 7.4.5		7.2.1 7.4	Sample collection equipment Sample collection session record Determination of requirements related to the product Purchasing
Documentation Templates on WADA's website					Doping Control Forms Whereabouts Forms
IADA 301	Recommended specifications for purchasing laboratory services		6.1 6.4	7.2.1 7.4	Use of Approved Laboratories Standards for Sample Analysis and Reporting Determination of requirements related to the product Purchasing
IADA 302	Recommended specifications for purchasing transport services	9.0		7.2.1 7.4	Transport of samples and documentation Determination of requirements related to the product Purchasing